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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,952

09/08/2004

Celal Albayrak

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/506,952

Applicant(s)

ALBAYRAK, CELAL

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response of 1/22/07 is acknowledged. Claims 1-9 are pending and examined on the merits.

Election/Restrictions

As before, Applicant's election with traverse of the species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide in the reply filed on 07/24/2006 is acknowledged. The traversal is on the ground(s) that 1) the groups should be examined together, and 2) a species election is improper because all species of the genres (active agent/polymer) are sought for the claimed invention. The Examiner is unclear on the traversal. As to 1) above, all claims 1-11 are a single group with only a species election required, thus any groups that may be separable therein, have not been delineated, and the traversal is deemed a moot issue. Likewise, as to 2), all species will be examined in turn, assuming the elected species (and later searched species thereafter) are found to be free of the art. A species election is merely a starting point upon which a search and examination on the merits may commence. Thus, the traversal of the species election is deemed a moot issue as well.

However, as to the species election requirement, it is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchinson (US 5,889,110).

Hutchinson teach a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide, involving precipitating goserelin acetate and the polymer from solution/solvate by the use of DMSO (cryoprotectant) and then reconstituting and forming microparticles (see entire document, especially Examples 1-6 and Claim 16 method).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson (US 5,889,110) in view of Bhagwatwar et al. (US 20030049320) and Yeh et al. (US 5869103, cited by International Authority in related PCT Search Report).

Hutchinson is discussed above (see entire document). Due to the present claims amorphous language, it is unclear whether the steps of Hutchinson, in various examples, expressly teach the “effecting precipitation” step as comprising an L1/L2 combination wherein the latter is increased over the former (Applicant’s claims 2-4). It is clear Hutchinson teach

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L1/L2, wherein the latter is increased, following a precipitation step, and wherein the L2 is a non-solvent to the goserelin acetate (see e.g. claim 16, step iv)). This seems to be the only issue, as to whether Hutchinson expressly teaches within one of the examples this stepwise approach, or whether such would have been merely obvious. Additionally, it is not clear whether Hutchinson teach volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents combined in step (b) (Applicant's claim 7).

As previously discussed, Bhagwatwar et al. teach a method of forming microparticles comprising the elected species of active substance goserelin acetate and polymer poly-DL-lactide-co-glycolide (e.g. para 158, claims 8, 26, 37, and 47), with any suitable solution/solvent well known in the art (e.g. para 2-5, 40, 75, entire document), and contemplating any well known microparticle size well known in the art for the use of microparticles in vivo. Bhagwatwar et al. teach microparticles, but does not expressly teach that microparticles includes the species nanoparticles and specific size ranges under 1 μm , was not expressly found therein (e.g. Applicant's claim 11).

As previously discussed, Yeh et al. teach the formation of nano/microparticle, which comprises active substances and the polymer poly-DL-lactide-co-glycolide, including in size ranges less than 1 μm (e.g. col. 1, col. 3, lines 35-41, entire document).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at an L1/L2 solvent mixture as part of the "effecting precipitation" step, in Hutchinson, because Hutchinson advantageously teach various steps and means of carrying out the same ultimate goal of microparticle formation comprising active substance goserelin acetate within polymer poly-DL-lactide-co-glycolide, and further in view of the advantageous teachings

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of Bhagwatwar et al., using different steps to carry out the same and Yeh et al. to arrive at size limitations within that contemplated herein.

Likewise, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a volume fraction of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide of Hutchinson, either alone or in view of Bhagwatwar et al. or Yeh et al., because Hutchinson advantageously teach routinely optimizable amounts of the solutions/solvents therein, as do the latter references, to carry out the desired results of the artisan and the selection of the aqueous surfactant solution ranges between 60 and 80% of the aqueous and organic solvents in the initial mixing of the goserelin acetate-polymer poly-DL-lactide-co-glycolide, would have merely obvious depending on the results sought, absence evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claims 1-9 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed 9/8/04, namely the Examples in the original specification. In that paper, the steps seem to be different/distinct from that expressly, extremely broadly claimed (particularly as to the "effecting precipitation step, L1/L2 solvents thereto), and raises doubts as to whether the invention is different from what is defined in the claim(s).

The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained in part for the reasons of record, as to how the invention is carried out/with what. [It is noted that new art of record Hutchinson (US 5,889,110) is deemed to teach some, if not all the claims].

In e.g. claim 1, it remains unclear as claimed how Applicant is "effecting precipitation" (e.g. any differently than Hutchinson via use of freezing and cryoprotectants, like Applicant's own Examples (e.g. Ex. 1-3, using DMSO, cyroprotectant)?

In claims 2-4, it is unclear what the agents and amounts are contemplated as L1 and L2 are? The specification was not found to lend ample support to clarify this matter. Due to the uncertainty of this step and the agents/amounts, it was unclear how L1 and L2 distinguish themselves as not being obvious over the teachings of Hutchinson. In other words, until the invention is distinctly claimed (or clear specification guidance, e.g. examples provided), it is unclear what the invention is.

Specification

The disclosure is objected to because of the following informalities:

As applied in compound/pharmaceutical applications, the use of the trademark names is discouraged, if not improper in some situations, since product contents/compounds may change while Trademark names remain the same. In the present Examples, the Trademark name Resomer® 756 is improper. The common name, and elected compound poly-DL-lactide-co-glycolide should be used. See e.g. MPEP 608.01(v) and other relevant sections on the use of trademarks in patent specifications

Appropriate correction is required.

Conclusion

No claims are allowed.

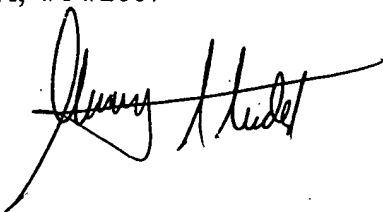
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 4/14/2007

A handwritten signature in black ink, appearing to read "Maury Audet", written in a cursive style.

MAURY AUDET
PATENT EXAMINER